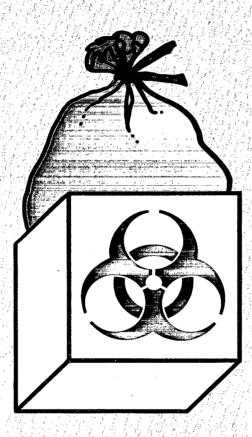


Managing and Tracking Medical Wastes

A Guide to the Federal Program for Generators



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Introduction

In response to the growing public concern over mismanagement of medical wastes, Congress enacted the *Medical Waste Tracking Act*. The Act charges the Environmental Protection Agency with responsibility for implementing a two-year demonstration medical waste tracking program that will help determine the best medical waste management procedures for the future. The program's goal is to find an effective means to ensure that regulated medical wastes get from their point of generation to their point of disposal.

Generators of regulated medical wastes will be part of the new demonstration tracking program in the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. Transporters and facilities that store, treat, destroy, and dispose of these wastes will also be part of the program.

This guide offers general information about the tracking program (Section 1) and specific instructions for regulated medical waste generators (Section 2). Section 2 includes requirements for generators of more than 50 pounds a month, such as hospitals, and special requirements for those producing less, such as physicians, dentists, and veterinarians. Separate guides in this series are provided for transporters and for facilities that treat, destroy, and dispose of regulated medical wastes.

This guide describes the federal program only. It is designed to help generators comply with the program. For more complete information, generators should refer to "Standards for the Tracking and Management of Medical Waste," interim final rule (40 CFR Part 259). In addition, states participating in the program have their own rules for managing medical waste. The Appendix lists addresses and phone numbers for offices in participating states and for EPA Regional Offices.

For additional copies of *Managing and Tracking Medical Wastes* or a copy of 40 CFR Part 259, call the RCRA Hotline at (800) 424-9346 or, in Washington, D.C., 382-3000.

The cooperation of all participants in the management of regulated medical waste will assure the success of this important demonstration program and reduce public exposure to the waste.

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The Medical Waste Tracking Program

In response to public concern over the mismanagement of medical wastes, the *Medical Waste Tracking Act* was enacted in the fall of 1988. The law directs the Environmental Protection Agency (EPA) to establish a two-year demonstration program for tracking medical wastes.

Under this law, EPA has issued regulations entitled "Standards for the Tracking and Management of Medical Waste" (40 CFR Part 259). The regulations list the medical wastes to be tracked and cover standards for separating, packaging, and labeling medical wastes before sending them for treatment or disposal. The results of the demonstration program are intended to help determine whether such a program should be extended nationwide.

The Medical Waste Tracking Act amends the Resource Conservation and Recovery Act (RCRA) by adding Subtitle J. It defines medical waste as "... any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals..."

Participating in the demonstration program are the States of Connecticut, New Jersey, New York, and Rhode Island, and the Commonwealth of Puerto Rico. The regulation is an interim final rule. It will be in effect for two years, until June 22, 1991. In Connecticut, New Jersey, and New York, the program is effective beginning June 22, 1989; in Rhode Island and the Commonwealth of Puerto Rico, the program is effective beginning July 24, 1989.

The demonstration program involves **only** regulated medical wastes **generated in one of the states** participating in the program, even when these wastes leave the state. The program sets up a system for tracking the waste from the generator to the disposal site. A tracking form that accompanies this waste is signed and a copy is retained by a representative of the waste generator and each transporter, transfer station, and treatment, destruction, and disposal facility handling it. When the final disposer—the destination facility—accepts the waste, a copy of the signed tracking form is returned to the generator. In this way the generator is assured that the waste was received for disposal. The tracking system includes "exception" and "discrepancy" reporting to alert EPA and the states if wastes are not being handled properly.

To minimize contact with regulated medical wastes by workers, handlers, and the public, the program includes specific requirements for segregating, packaging, labeling, marking, and storing medical wastes before they are shipped to another site for treatment, destruction, or disposal. Other requirements include recordkeeping, reporting, and enforcement. EPA will evaluate the success of the program and report the results to Congress.

Waste Managers Participation This booklet is intended to help generators comply with the federal rules in the participating states. Generators of regulated medical waste in these states must also follow rules required by the individual states. Generators should check with their state officials for clarification of state rules. While participating states use the same basic tracking form as EPA's, some states might regulate more wastes or require special permits or licenses. In addition, individual states might not recognize some of the special exceptions allowed under EPA rules. Participating states are authorized to enforce this program.

The demonstration program also includes owners and operators of treatment, destruction, and disposal facilities that manage waste generated in a participating state, even if their facilities are located in a nonparticipating state. Similarly, the program includes transporters carrying regulated medical waste from a participating state, even if the waste is then taken to a nonparticipating state. The program includes vessels and transporters that take medical wastes to shore from ships docked in participating states. Federal facilities generating regulated medical waste in participating states are also covered under this program.

Regulated Medical Wastes

Medical wastes affected by the pilot program include

- cultures and stocks of infectious agents.
- human blood and blood products.
- human pathological wastes, including those from surgery and autopsy.
- · contaminated animal carcasses from medical research.
- wastes from patients isolated with highly communicable diseases.
- all used sharp implements, such as needles and scalpels, and certain unused sharps.

These regulated medical wastes fall into two categories: untreated or treated. The Glossary provides detailed descriptions of these medical wastes.

The demonstration program focuses on wastes that historically have been improperly managed and are most likely to pose a substantial threat to human health and the environment. However, any additional waste that a health care professional believes may pose a risk should be handled as a regulated medical waste.

Mixtures of regulated medical waste and general trash are regulated as medical waste. Mixtures of regulated medical waste and hazardous waste are usually regulated as hazardous waste. However, if medical waste is mixed with hazardous waste, which falls under the small quantity hazardous waste exemption, then the waste mixture must be tracked as medical waste under this program.

Pre-transporting Procedures

Regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be properly prepared for shipping. First, the wastes must be separated from general trash, and then sharp items, fluids, and other medical wastes must be separated from each other. They are then packaged to prevent tearing, breaking, or leaking during shipping and handling.

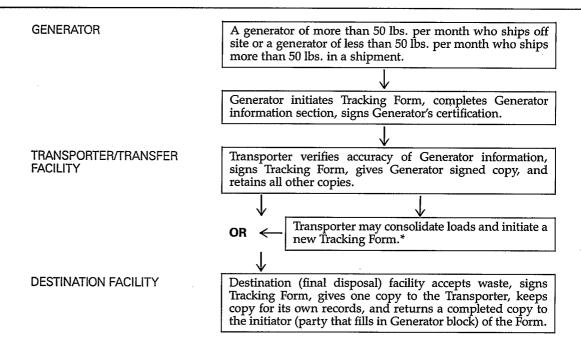
Packages are to be labeled and marked to identify the contents of the package and the generator and transporter of the waste. In addition, stored wastes must be maintained to prevent them from coming into contact with workers or the public.

Tracking Regulated Medical Wastes

At the core of the medical waste demonstration tracking system is a Medical Waste Tracking Form (see Figure 1). This form must accompany each off-site shipment that weighs 50 pounds or more. Shipments from generators of less than 50 pounds a month may be combined onto one tracking form by the transporter. Generators, transporters, and treatment, destruction, and disposal facilities are responsible for filling in, forwarding, and retaining a copy of this form for their records. Figure 2 illustrates how the medical waste tracking system works.

MEDICAL WASTE TRACKING FORM					INSTRUCTIONS FOR COMPLETING MEDICAL WASTE TRACKING FORM	1	
	1. Generator's Name and Mailing Address		2. Tracking Form Number 4. State Permit or ID No. 6. Telephone Number ()		Copy 1 — GENERATOR COPY: Mailed by Destination Facility to Generator Copy 2 — DESTINATION FACILITY COPY: Retained by Destination Facility Copy 3 — TRANSPORTER COPY: Retained by Transporter Copy 4 — GENERATOR COPY: Retained by Generator		
	3. Telephone Number ()				As required under 40 CFR Part 259: 1. This multicopy (4-page) shipping document must accompany each shipment of regulated medical		
	5. Transporter's Name and Mailing Address	6. Telephone N			waste generated in a Covered State. ltems numbered 1-14 must be completed before the generator can sign the certification. Items 4, 10, 11c, & 19 are optional unless required by the State. Item 22 must be completed by the destination facility. For assistance in completing this form, contact your nearest State office or Regional EPA office, c		
	7. State Transporter Permit or ID No.				call (800) 424-9346. 16. Transporter 1 (Certification of Receipt of Medical Waste as described in items 11, 12, & 13)		
	8. Destination Facility Name and Address	9. Telephone N	9. Telephone Number () 10. State Permit or ID No.		Printed/Typed Name Signature Date	-	
В О		10. State Perm			17. Transporter 2 or Intermediate Handler (name and address)		
ERAT	11. US EPA Waste Description	12. Total No. Containers	13. Total Weight or Volume	POR	CO 19. State Transporter Permit or ID No.		
E E	a. Regulated Medical Waste (Untreated)		· <u>.</u>	ANS	z		
	b. Regulated Medical Waste (Treated)	-		TR/	20. Transporter 2 or Intermediate Handler (Certification of Receipt of Medical Waste as		
	c. State Regulated Medical Waste				Printed/Typed Name Signature Date	-	
	14. Special Handling Instructions and Additio	nal Information			21. New Tracking Form Number (for consolidated or remanifested waste)		
				N O	_ _	13)	
	15. Generator's Certification: Under penalty of criminal and civil prosecution for the making or submission of false statements, representations, or omissions, I declare, on behalf of the generator———————————————————————————————————				Printed/Typed Name Signature Date (If other than destination facility, indicate address, phone, and permit or ID no. in box 14.)	-	
					23. Discrepancy Box (Any discrepancies should be noted by item number and initials)		
					۵		

 $FIGURE\ 1.\ Medical\ waste\ tracking\ form.$



*Initiators of Tracking Forms become generators in effect under this Tracking System.

FIGURE 2. Medical waste tracking system. All medical waste shipments that must be accompanied by a tracking form are tracked from generator to final disposal, or destination facility.

The Waste Management System

Because it is helpful for those involved in the demonstration program to understand the roles of generators, transporters, and facilities, their roles are described here.

Generators

A person or institution located in a participating state, generating 50 pounds or more of regulated medical waste monthly and shipping it off site, is fully covered by the demonstration program. These generators must separate, package, label, mark, and track medical wastes according to the regulation.

Generators producing and shipping less than 50 pounds a month must also prepare their wastes properly for shipment. They may use a log to account for wastes, however, instead of a tracking form.

On the other hand, generators that dispose of waste on site or in the sewer system are not covered by the requirements of this program. Generators that treat and destroy waste on site, such as by incineration, are subject to certain reporting and recordkeeping requirements. Wastes that are treated and destroyed or disposed of on site or in sewers are not counted as part of the limit of 50 pounds per month. All medical wastes—even those treated, destroyed, and disposed on site—must be stored properly.

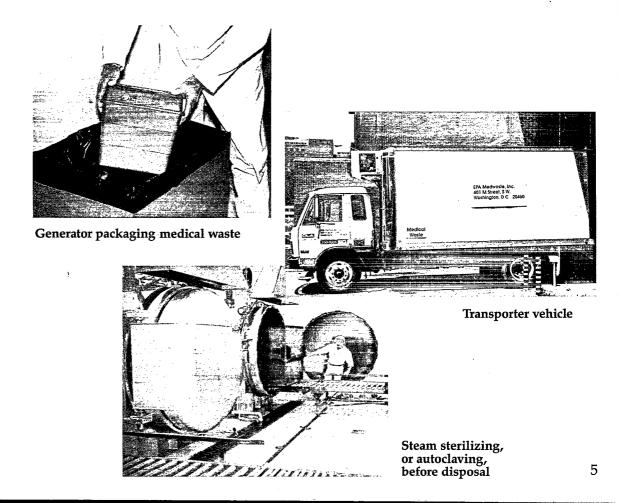
Transporters

Transporters must notify EPA of their intention to comply with the program to be allowed to accept regulated medical wastes for transport. EPA maintains a list of transporters who have notified EPA of their intent to transport regulated medical wastes generated in each participating state. This list is available to generators. Transporters must follow rules governing their vehicles and addressing tracking, recordkeeping, and reporting of waste shipments. They must also make sure that wastes they pick up have been properly prepared for shipping and that the tracking form is accurate.

Treatment, Destruction, and Disposal Facilities

The demonstration tracking program rules apply to owners and operators of treatment, destruction, and disposal facilities receiving regulated medical wastes. These facilities include incinerators, landfills, and treatment operations that grind, steam sterilize, or treat the waste with disinfectants, heat, or radiation.

Like generators and transporters, treatment, destruction, and disposal facilities must keep track of medical wastes and maintain records. Facilities must send a signed copy of the tracking form back to the generator or initiator of the tracking form when the wastes have been accepted for disposal. The facility owners or operators must investigate any discrepancies between the accompanying papers and the shipments they receive; if, after investigation, there is still a discrepancy, they must report it to EPA and the generator state agency.



A Detailed Guide for Generators of Regulated Medical Wastes

This section includes instructions for generators of regulated medical wastes to help them comply with the federal regulations. It outlines requirements for generators of more and less than 50 pounds a month. Checklists are included.

Profile of a Generator

Health care providers, veterinarians, research laboratories, and establishments involved in treating, diagnosing, or immunizing humans or animals probably generate medical wastes. (Table 1 presents some examples of regulated medical wastes that might be generated.) If so, they have to determine how they are affected by the medical waste demonstration tracking program. To understand their responsibilities, these generators must determine which of their wastes are regulated. They must then keep track of the quantity of regulated medical waste they generate and of how they dispose of it. All generators are affected by the program, but some may be subject only to certain parts (see Table 2).

A hospital is considered a single generator even though there might be many practitioners on staff, each producing medical waste. In contrast, a medical building shared by several practitioners, each with independent practices, is not a single generator; each practitioner is a generator.

TABLE 1. Examples of medical wastes generated by institutions or practitioners

Institution/Practitioner	Medical Wastes
Family physician	Syringes; tissue removed during minor surgery.
Dentist	Disposable needles; teeth and tissue. (Teeth given back to children are not considered waste in this program.)
Veterinarian	Syringes used for vaccination.
Hospital	Blood-soaked materials from the emergency room; needles, syringes, scalpels; amputated limbs and other body parts from surgery; and IV bags from patient-care rooms.
Laboratory	Blood vials; glassware that was in contact with infectious agents; discarded body fluids or specimens.



Generator marking box

Generators Subject to All Requirements

The following generators must comply with all program requirements.

Persons, institutions, or companies that

- are located in a participating state.
- generate 50 pounds or more of regulated medical waste monthly on site (on a contiguous piece of property).
- ship that waste off site for treatment, destruction, or disposal.

Vessels at port in a participating state where regulated medical wastes are taken to shore for transport and disposal. These vessels operate as co-generators with their shore bases, thus sharing responsibilities under the program.

Generators subject to the full requirements must

- follow all pre-transporting requirements: segregate, package, label, and mark.
- initiate a tracking form to track their wastes.
- use a transporter that has notified EPA of its intent to participate.
- comply with recordkeeping and reporting requirements.

TABLE 2. Medical waste generator requirements

Generator of	Pre-Transportation Requirements	Tracking and Reporting	Transporting	Recordkeeping
> 50 lb./month shipping waste off site	Must follow requirements.	Must use Tracking Form ¹ and file Exception Reports, if necessary.	Must use transporter that has notified EPA of intent to participate.	Must comply with recordkeeping and reporting requirements.
< 50 lb./month shipping > 50 lb./month off site in a shipment	Must follow requirements.	Must use Tracking Form ¹ and file Exception Reports, if necessary.	Must use transporter that has notified EPA of intent to participate.	Must comply with recordkeeping and reporting requirements.
< 50 lb./month shipping < 50 lb./month off site ³	Must follow requirements.	May maintain a Log instead of using a Tracking Form; not required to file Exception Reports.	Must use transporter that has notified EPA of intent to participate or use own vehicle or mail (sharps) by U.S. Postal Service.	Must comply with recordkeeping and reporting requirements.

¹Except when shipping within institutions or company.

Generators with Special Requirements and Exemptions

Generators must determine the quantity of regulated medical waste they generate and ship off site in a month to see if they qualify for the special requirements or exemptions for small generators. Wastes disposed of on site or in sewers are not counted or tracked. Wastes that have been both treated and destroyed on site, such as incinerator ash, are not tracked either. Table 3 outlines generator exemptions and special requirements.

Pre-transporting Procedures

All regulated medical wastes that are to be transported to an off-site facility for treatment or disposal must be segregated and separated, packaged, labeled, and marked.

Segregating and Separating Wastes

Before packaging, medical waste generators must segregate the waste from general trash. If general trash is placed in a container with regulated medical waste, the trash must be handled as a regulated medical waste. Once segregated from general trash, medical waste must be separated to the extent practical into the following groups:

- sharps, such as needles, scalpels, glassware, and syringes, with residual fluids.
- fluids in quantities greater than 20 cubic centimeters.
- other regulated medical wastes such as body parts, blood-soaked bandages, and research animal carcasses.

²Only when taking wastes to generator's place of business, or to a hospital or other facility with which there is a contract.

³See Table 3.

		PRE-TRANS	PORTING					
Generator	Packaging	Labeling	Marking	Storing	Tracking	Transporting	Disposing	Recordkeeping
< 50 lb./month shipping < 50 lb./month off site ¹	Must Must follow follow rules. rules.		Must Must follow rules. rules.		Exempt from using Tracking Form; must maintain a log. ²	Must use transporter on EPA list or own (or authorized employee's) vehicle or send sharps by U.S. Mail.	If using own vehicle, must take wastes to own place(s) of business, a hospital, or a treatment destruction, or disposal facility with which there is an agreement.	Must maintain log for three years.
Institutional, with satellites or branches ³	Must follow rules.	Must follow rules.	Must follow rules.	Must follow rules.	Exempt from using Tracking Form; must maintain a log.4	Must use transporter on EPA list or use own (or authorized employee's) vehicle	Must transport waste from a satellite or branch operation—original operation point—to central collection point within the same state.	years.
< 50 lb./month sending < 50 lb. of sharps/ month by U.S. Mail	Must follow rules.	Must follow rules.	Must follow rules.	Must follow rules.	Exempt from using Tracking Form; send by registered mail, return receipt requested, showing delivery date and receiver's name and address; keep log. ⁵	N/A	N/A	Must maintain receipt and log for three years.
Treating and destroying or disposing of wastes on site	Exempt	Exempt	Exempt	Must follow rules.	Must maintain log if waste treated and destroyed on site by method other than incineration.	N/A	N/A	Must maintain log for three years.
Incinerating own waste on site	Exempt	Exempt	Exempt	Must follow rules.	Must comply with record- keeping and reporting requirements (40 CFR Part 259, Subpart G).	N/A	N/A	N/A

¹Figure 3 shows how a small generator might manage medical wastes.

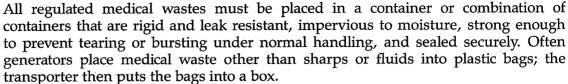
²See Figure 4.

³Exemption ends when waste is shipped off site from central collection point. ⁴See Figure 5.

⁵Log must show date, name and address of facility, weight, and category of waste.

Clog must show weight of all waste treated and approximate percentage that is medical.

Packaging Regulated Medical Wastes



Sharps and fluids may also be boxed by the transporter. But first sharps, such as needles and scalpels, must be packaged in a rigid container resistant to punctures; fluids must be poured into a container resistant to breaking and equipped with a tightly fitting stopper or lid.

Oversized medical waste—animal carcasses and other items too large for standard bags and containers—should be handled and transported, minimizing contact with transportation workers, other handlers, and the public.

Non-rigid packaging and inner liners, such as plastic bags, are likely to become contaminated through use. Therefore, they are considered regulated medical waste and may not be reused. Rigid containers, including bins, barrels, and boxes can be reused, but must be made free of any visible contamination. If rigid containers cannot be cleansed of visible contamination, then they too are handled as regulated medical wastes.

Example 1

Doctors in a small group medical practice accumulate used needles and syringes, cultures of infectious agents, and other regulated medical wastes resulting from tests or out-patient surgery. They plan to dispose of the wastes off site. Because the doctors are in a group practice, the waste from each is added together. They must make sure that the wastes are segregated from other trash and are packaged and labeled properly at the office where they first became medical wastes. The wastes from their combined practice amount to less than 50 pounds a month. One of the doctors carries it in his own private car to a hospital where it is incinerated. The small group practice must have a written agreement that the facility will accept the waste, and they must maintain a log for three years. The log contains the weight and category of the medical waste, its date of shipment, the name and address of the facility receiving the waste, and the signature of the doctor who transported the waste to the facility.

Example 2

The same group medical practice arranges to have the waste picked up by a transporter on the EPA notification list. In this case, the doctors are responsible for preparing the waste for shipping and keeping the doctors' office log. One of the doctors can assume the paperwork duties and make all the arrangements, but the group of doctors remains responsible for all the wastes.

Example 3

Several doctors have unrelated practices in a single medical building. Each practice produces less than 50 pounds of medical waste in a month. The doctors choose to arrange for a single transporter. In this case, each doctor keeps a separate log and packages, labels, and marks his or her waste properly.

FIGURE 3. Examples for small generators: physicians, veterinarians, dentists, and other health services.





GENERATOR SHIPMENT LOG

Transporter Name and Address	Transporter State Permit or ID Number	Quantity and Cat Waste Transpo Containers	Date of Shipment	Signature of Representative Accepting Waste for Transport
***************************************		Untreated	, ,	
		Treated		
		Untreated	, ,	
		Treated	 	
		Untreated	, ,	
		Treated	 	
		Untreated	, ,	
		Treated		
	:	Untreated	, ,	
		Treated	 _/_/_	
		Untreated	 , ,	
		Treated	 	
		Untreated	, ,	
		Treated	 _//_	

FIGURE 4. Generator shipment log for generators of less than 50 pounds of regulated medical waste per month, who ship less than 50 pounds per shipment.

OPERATING LOG—ORIGINAL GENERATION POINT

- Date of shipment.
- Weight of waste transported, by category: treated or untreated.
- Address/location of central collection point.
- Signature of the generator's employee who accepts and transports the waste.

OPERATING LOG—CENTRAL COLLECTION POINT

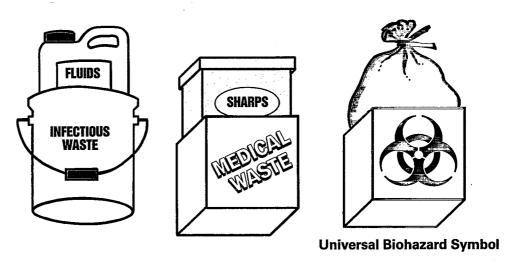
- Date of receipt.
- Quantity by weight and waste category (treated or untreated) accepted, by category.
- Address/location of original generation point.
- Signature of operator who accepts the waste.

The logs are retained for three years.

FIGURE 5. Log for institutions transporting between their own facilities.

Labeling

Generators shipping untreated medical wastes are required to label packaging, or containers, to alert handlers. Generators must affix a water-resistant label to all packaging of untreated wastes. When there is inner and outer packaging, or containers, each container of waste must be labeled INFECTIOUS WASTE or MEDICAL WASTE or display the universal biohazard symbol as illustrated below. Red plastic bags, when used as inner packaging for untreated wastes, need no labels. However, the outer packaging must still carry the proper label or symbol.



Treated medical wastes do not require such warning labels, but must be marked as specified below.

Marking

Before shipment, all packaging—inner and outer—must be marked with indelible ink or with a water-resistant identification tag. Each inner container, if used, must show the name and identifying numbers or address of the generator. Each outer container must identify the contents as medical waste and include the information as it appears on the sample tag shown below.

		MEDICAL WASTE		
(GENERATOR	Date of Shipment: 8/1/89		
	Name	General Hospital		
	Address	Firstaid Avenue		
	_	Hollywood, N.J. 00000		
٦	TRANSPORT	ER:		
	Name	We-Haul MedWaste		
	Address_	123 Haula Way		
		Towtown, Anystate 00000		
				
MEDICAL WASTE				

Storing Medical Wastes

Some facilities store their medical wastes before disposing of them on site or sending them to another location for disposal. Stored medical waste must be

- · protected from water, rain, and wind.
- kept nonputrescent.
- kept in locked dumpsters, sheds, tractor trailers, or other secure containers, if outdoors.
- protected from unauthorized employees and animals and pests.

Tracking Medical Wastes

The full tracking system (see Figure 6), including tracking forms, must be used if

- generators of 50 pounds or more a month, including vessels, transport regulated medical waste off site.
- generators of less than 50 pounds a month ship 50 pounds or more in a single shipment.

For generators that initiate tracking forms, a tracking form may be obtained from different sources, depending on the waste destination. If the waste is shipped to a participating state, which prints the form, the transporter must provide that state's form to the generator. If the waste is shipped to a nonparticipating state or a state that does not print the form, the generator must get the form from its own state. But if the generator state does not require its own form, the generator may reproduce the tracking form in this booklet or obtain a copy of the federal form from another source, such as the transporter.

Preparing a Tracking Form

The generator must prepare enough copies of the tracking form for itself, transporters as required, all intermediate handlers, the owner or operator of the final facility accepting the waste, and one copy to be returned to the generator. Each handler keeps a copy for its own records. When the final disposal site or destination facility accepts the waste, a copy is returned to the generator with all signatures in place.

The tracking form is usually a four-part form: Copy 1 travels with the waste and is returned to the generator by the destination facility; copy 2 is retained by the destination facility; copy 3 is retained by the transporter; and copy 4 is held by the generator when the waste is released for transport. If more than one transporter is used or an intermediate handler is required, then enough copies of the form are needed for each to keep a copy. More specific instructions appear in 40 CFR Part 259, Appendix I. If shipping by rail directly from the site, a generator should refer to 40 CFR 259.52(e) for specific instructions.

Exception Reporting

Within 35 days, the generator should receive a copy of the completed tracking form bearing the signature of the destination facility's owner or operator. If a form is not received, a generator must try to determine the location of the waste.

If, after 45 days, a signed tracking form is still not received, then an Exception Report must be filed by the next day with the state and the EPA Regional Administrator. The Exception Report includes both a letter from the generator explaining its efforts to locate the waste and the results of such efforts, and a legible copy of the original tracking form.

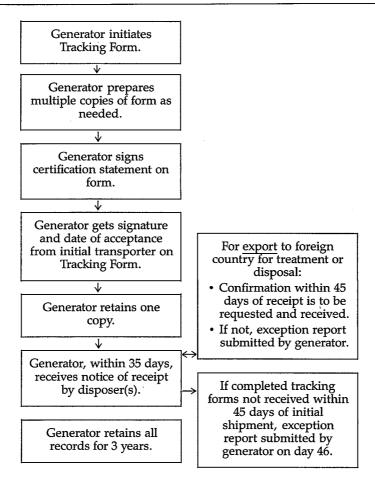


FIGURE 6. Tracking medical wastes.

Exporting Medical Wastes

Generators exporting regulated medical waste to another country for treatment, destruction, or disposal must request written confirmation from the destination facility that the waste was received. If notification has not been received within 45 days, the generator has to submit an Exception Report by the 46th day.

Keeping Records

As part of routine recordkeeping, generators using the tracking system are to maintain information for three years about medical waste transporters with whom they contract. These records must include copies of all tracking forms. All logs, receipts, and Exception Reports must also be retained for three years. EPA or state agencies may ask to inspect these records or ask the generators to provide copies.

Other Reports

EPA may require generators to provide additional reports concerning quantities of regulated medical waste and their management methods. Furthermore, EPA may require an inspection of a generator's premises.

Medical Waste Generator Checklists

Do These Rules Apply To You?

A "person" under these rules is an individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.

######################################	Person generates regulated medical waste in a participating state. (If yes continue.)
	Port receiving regulated medical waste from a vessel is located in a participating state. (If yes, continue.)
	Vessel from which regulated medical waste is carried to shore in a participating state. (If yes, continue.)
	Person generates on site 50 pounds a month or more of regulated medical waste and sends it off site. (If yes, continue to Full Requirements Checklist.)
	Person generates less than 50 pounds a month, but ships more than 50 pounds in a shipment. (If yes, continue to Full Requirements Checklist.)
	Person incinerates medical waste on site. (If yes, see 40 CFR Part 259, Subpart G.)
	Person generates regulated medical waste and treats and destroys it on site. (If yes, exempt from this program for that waste, except for maintaining a log. May be subject to state regulations.)
	Person transports within its own facility's branch or satellite operations—from generation point to central collection point. (If yes, exempt from tracking requirements and certain transporting requirements. See Figure 5 Log.)
	Person generates less than 50 pounds a month and sends off site less than 50 pounds in a shipment. (If yes, see Figures 3 and 4, and Small Generator Checklist.)
	Person generates less than 50 pounds a month and uses U.S. Postal Service to transport sharps. (If yes, see specific requirements and Small Generator Checklist.)

Full Requirements Checklist

comply.

Shipments of More than 50 Pounds

If you are subject to the full requirements, the following list is designed to help you

· 1 · ·		Do you separate regulated medical waste from general trash?
	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Do you separate sharps and fluids from each other and from other regulated medical wastes?
		Are sharps in puncture-resistant containers and are fluids in break-resistant, tightly-lidded or stoppered containers?
		Are all IV bags and sharps, such as needles and syringes, from patient-care rooms included as regulated medical waste?
•		Are the packages rigid, resistant to leaks, impervious to moisture, strong enough to prevent tearing or bursting, and sealed?
'	***************************************	Are they properly labeled and marked?
		Do you store these wastes properly while awaiting shipment?
	· · · · · · · · · · · · · · · · · · ·	Do you contract with a transporter on the EPA notification list?
٠	,	Do you have enough copies of the tracking form so that each transporter, intermediate handler, and the destination facility may retain a copy, with one left over to be sent back to you for your recordkeeping requirements?
	. ———	Do you fill out the form accurately and sign the certification box? (See 40 CFR Part 259, Appendix I: Medical Waste Tracking Form and Instructions.)
		Do you get a signature from the first transporter along with your copy of the signed form?
	Do you ur	derstand that
		Your copy of each tracking form is to be retained for three years?
		When the waste is accepted at a destination facility a copy of the completed, signed tracking form should be received within 35 days and, if it has not:
		 It is your responsibility to find out what happened to the waste; and You must file an Exception Report if a completed tracking form is not received within 45 days?
		You must allow EPA inspection, if requested?
		You must also follow all applicable state and local regulations?

Small Generators Checklist

Generators of Less
Than 50 Pounds Per
Month Who Ship
Less Than 50 Pounds
Per Shipment

If you are a small generator, the following list is designed to help you comply with the requirements.

 Do you keep regulated medical wastes separate from general trash?
 Do you separate sharps and fluids from each other and other regulated medical wastes?
 Are sharps in puncture-resistant containers and are fluids in break-resistant, tightly-lidded or stoppered containers?
 Are the packages rigid, resistant to leaks, impervious to moisture, strong enough to prevent tearing or bursting, and sealed?
 Are they properly labeled and marked?
 Do you store these wastes properly while awaiting shipment?
 Do you contract with a transporter on the EPA notification list;
OR
Do you personally take the waste in your own vehicles to a hospital or other facility that has agreed to accept it?
 If so, do you record the shipment in a log (see Figure 4)?
OR
 Do you mail sharps using the U.S. Postal Service, keeping receipts and an operating log?
 Do you understand that you must retain records for three years?
 Do you understand that you must also follow applicable state and local rules?

Glossary

Cultures and Stocks

Following are the classes of regulated medical wastes and a description of each.

Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

Pathological Wastes

Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.

Human Blood and Blood Products

Liquid waste human blood; products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.

Sharps

Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories. These include hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

Animal Waste

Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

Isolation Wastes

Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

Unused Sharps

The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

Biologicals

The following terms are defined here to address the management of medical wastes. They may be different from those federal definitions used for solid or hazardous waste.

Blood Products

Preparations made from living organisms and their products, including vaccines, cultures, etc. intended for use in diagnosing, immunizing, or treating humans or animals, or in related research.

Body Fluids

Any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon. Liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial,

Central Collection Point

pleural, peritoneal, and pericardial fluids; and semen and vaginal secretions. A location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site or its treatment on-site.

Container

Any portable device in which a material is stored, transported, disposed of, or otherwise handled. The term container, when describing the packaging requirements, does not include items that are regulated medical waste.

Decontamination

The process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.

Destination Facility

The disposal facility, the incineration facility, or the facility that both treats and destroys regulated medical waste to which medical wastes are shipped.

Destroyed Regulated Medical Waste Regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognizable as medical waste, but has not yet been treated. It does not mean compacted regulated medical waste.

Destruction Facility

Facility

A facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart.

All contiguous land and structures, other appurtenances, and improvements on the land used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist

of several treatment, destruction, storage, or disposal operational units.

Generator

Any person, by site, whose act or process produces regulated medical waste or whose act first causes a regulated medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity is a separate generator. [Note: see definition of "person."]

Infectious Agent

Any organism (such as a virus or a bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

Intermediate Handler

A facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term does not include transporters.

Laboratory

Any research, analytical, or clinical facility that performs health care-related analysis or service. This includes medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.

Landfill

A disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.

Medical Waste

Any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under 40 CFR Part 261 or any household waste as defined in 40 CFR §261.4(b)(1).

On-site

The same or geographically contiguous property which may be divided by public or private right of way, provided the entrance and exit between the properties is at a crossroads intersection, and access is by crossing as opposed to going along the right of way. Non-contiguous properties owned by the same person but connected by a right of way which he controls and to which the public does not have access is also considered on-site property.

Original Generation Point
Oversized Regulated
Medical Waste

Location where regulated medical waste first becomes waste (is "generated"). Medical waste that is too large to be placed in plastic bags or standard containers.

Package or Outside Package

The packaging/container and its contents.

Packaging

The assembly of one or more containers and any other components necessary to assure minimum compliance with the program's packaging requirements.

Person

An individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any department, agency or instrumentality of the United States.

Storage

The temporary holding of regulated medical wastes at a designated accumulation area before treatment, disposal, or transport to another location.

Transfer Facility

Any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held during the course of transportation. Also, a location in which medical waste is transferred between two vehicles.

Treated Regulated Medical Waste

Regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but that has not yet been destroyed.

Treatment

When used to refer to waste handling, it means any method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to substantially reduce or eliminate its potential for causing disease.

Appendix

Participating State Programs

Connecticut Department of Environmental Protection Solid Waste Management Unit

State Office Building 165 Capitol Avenue Hartford, CT 06106 (203) 566-5847 (Region I)

New Jersey Department of Environmental Protection Division of Solid Waste Management

401 East State Street, CN 414 Trenton, NJ 08625 (609) 984-7840 (Region II)

New York State Department of Environmental Conservation

50 Wolf Road Albany, NY 12233

Tracking form: (518) 485-8394 Other inquiries: (518) 457-3254

(Region II)

Rhode Island Department of Environmental Management

9 Hayes Street Providence, RI 02907-5003 (401) 277-2771 (Region I)

Puerto Rico Environmental Ouality Board

Box 11488 Santurce, PR 00910 (809) 722-0439 (Region II)

EPA Regional Offices

Region I State Waste Programs Branch

JFK Federal Building Boston, MA 02203 (617) 573-5758

Region II Air and Waste Management Division 26 Federal Plaza New York, NY 10278 (212) 264-5166

Caribbean Field Office (809) 729-6920

Region III Waste Management Branch 841 Chestnut Building Philadelphia, PA 19107 (215) 597-2842 Region IV Hazardous Waste Management Division 345 Courtland Street, N.E. Atlanta, GA 30365 (404) 347-3016

Region V RCRA Activities 230 S. Dearborn Street Chicago, IL 60604 (312) 353-9510

Region VI Air and Hazardous Materials Division 1445 Ross Avenue Suite 1200 Dallas, TX 75270

Region VII RCRA Branch 726 Minnesota Avenue Kansas City, KS 66101 (913) 236-2856

(214) 655-6652

Region VIII Waste Management Division999 18th Street, Suite 500
Denver, CO 80202
(303) 293-1496

Region IX Toxics and Waste Management 215 Fremont Street San Francisco, CA 94105 (415) 974-8388

Region X Waste Management Branch 1200 Sixth Avenue Seattle, WA 98101 (206) 442-6501 Office of Solid Waste
United States
Environmental Protection
Agency
401 M Street, S.W.
Washington, DC 20460

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